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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHRISTIAN, MARJORIE ELLEN

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,016	Applicant(s) WECHS, FRIEDBERT	
	Examiner MARJORIE CHRISTIAN	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 12/23/2008 has been entered and fully considered.
2. The information disclosure statement from 8/1/2006 has been fully considered.
3. Claims 1-12, 14-16 are pending and have been fully considered.

Oath/Declaration

4. Examiner withdraws objection to oath/declaration as unnecessary per 37 CFR 1.55 as no intervening reference is present.

Double Patenting

5. Claims 1-12, 14-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 10, 12-13, 16, 18-20 of copending Application No. 10/588,696. Although the conflicting claims are not identical, they are not patentably distinct from each other because both disclose a method and apparatus comprising a hollow fiber membrane with polyelectrolyte on the interior separating layer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 12, 14-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 18 of copending Application No. 10/588,695. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because both disclose a hollow fiber membrane with polyelectrolyte bound in the separating layer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

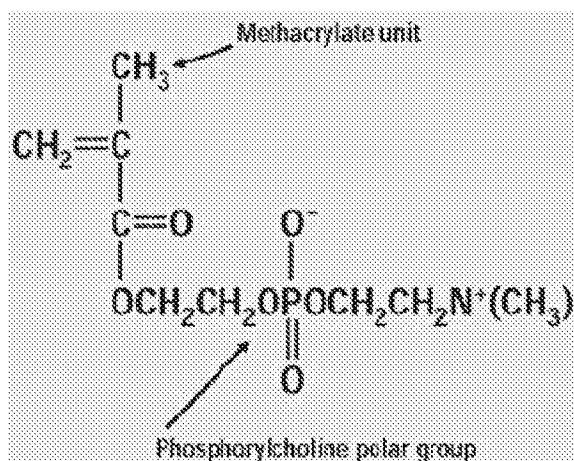
Claim Rejections - 35 USC § 102/103

6. **Claims 1, 4, 8-12, 14, 16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US PG Pub 2004/0045897, NAKABAYASHI et al. (hereinafter NAKABAYASHI) (where the PCT Publication WO02/09857 and EP 1 306 121 are related 102(b) date references) as evidenced by Developments in Medical Polymers for Biomaterials Applications, KATZ (hereinafter KATZ).**

As to Claims 1, 11, NAKABAYASHI discloses a process for producing a porous substrate (Abstract), comprising: preparing a casting solution of polymer and solvent; conversion of the solution into a shaped object with a first and second surface (Ex. 1-8); bringing the inner surface into contact with a precipitant system resulting in the formation of a separating layer on the inner surface (Pg. 2, Para. 15); and washing (Ex. 1-8); wherein the precipitant system includes MPC copolymer (2-methacryloyloxyethyl phosphorycholine), which contains a fixed negative charged group as evidenced by KATZ (shown below). The MPC co-polymer is zwitterionic and therefore has a net zero charge and may not expressly disclose the negatively fixed charge of the polyelectrolyte. However, NAKABAYASHI discloses inclusion of vinyl-polymerizable

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monomer (Formula 3, Pg. 3, Para. 23) wherein R8 is a hydrogen atom (negatively charged group) that is polymerized in the inner lumen dynamically during injection (Ex. 1-8). Therefore, in the alternative the MPC co-polymer with the negatively charged monomer (Formula 3) that polymerizes during injection at least renders obvious the polyelectrolyte with negative charge in the precipitant system.



As to Claim 4, NAKABAYASHI discloses that the dissolved interior filler precipitates in contact with the spinning solution (Ex. 1-8).

As to Claims 8-9, NAKABAYASHI discloses polysulfone polymer used as the membrane-forming polymer (Pg. 3, Para. 22).

As to Claim 10, NAKABAYASHI discloses the forming device is a hollow fiber die, which converts the spinning solution into a hollow-fiber with an inner and outer side (Ex. 1-8).

As to Claim 12, NAKABAYASHI discloses an integrally asymmetric membrane with a separating and supporting layer (Abstract, Pg. 3, Para. 15) comprising an interior filler comprising a negatively charged polyelectrolyte (MPC) wherein the outer layer is

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free from the interior filler (Ex. 1-8) and interior filler is physically bound in the separating layer (Pg. 4, Para. 36-37). The MPC co-polymer is a zwitteronic and has a net zero charge and may not expressly disclose the negatively fixed charge of the polyelectrolyte. However, NAKABAYASHI discloses inclusion of vinyl-polymerizable monomer (Formula 3, Pg. 3, Para. 23) wherein R8 is a hydrogen atom (negatively charged group) that polymerizes in the inner lumen dynamically during injection (Ex. 1-8). Therefore, in the alternative the MPC co-polymer with the negatively charged monomer (Formula 3) that is polymerized during injection at least renders obvious the polyelectrolyte with negative charge in the precipitant system.

As to Claim 14, NAKABAYASHI discloses that the separating layer faces the lumen (Claim 9, Pg. 6-7, Para 36-38), where it is implicit that the inner solution coagulates the membrane faster than air resulting in an inner separating layer.

AS to Claim 16, NAKAGASHI discloses that the membrane is chemically modified with an agent that reacts with the polyelectrolyte with negative fixed charges (Pg. 4-5, Para. 40-41).

Claim Rejections - 35 USC § 103

7. **Claims 1-12, 14-16** are rejected under 35 USC 103 (a) as being obvious over US Patent No. 4,604,208, CHU et al. (hereinafter CHU) in combination with US PG Pub 2004/0045897, NAKABAYASHI et al. (hereinafter NAKABAYASHI) (where PCT Publication WO02/09857 and EP 1 306 121 are related 102(b) date references) as

evidenced by Developments in Medical Polymers for Biomaterials Applications, KATZ (hereinafter KATZ).

As to Claims 1-3, 11, CHU discloses a process for producing a negatively charged microporous filter membranes (Abstract, C8/L16-18), comprising: preparing a casting solution of polymer and solvent (C7/L34-37); conversion of the solution into a shaped object with a first and second surface (C8/L34-38); extrusion over a fluid core (C8/L34-38); and washing (C8/L30-32). CHU discloses extrusion over a fluid core but does not specify the precipitant system brought into contact with the inner surface. However, NAKABAYASHI discloses bringing the inner surface into contact with a precipitant system resulting in the formation of a separating layer on the inner surface (Pg. 2, Para. 15), where the precipitant system includes MPC copolymer (2-methacryloyloxyethyl phosphorycholine), which contains a negatively charged group as evidenced by KATZ (shown above) and the inclusion of vinyl-polymerizable monomer (Formula 3, Pg. 3, Para. 23) where R₈ is a hydrogen atom (negatively charged group) that polymerizes in the inner lumen dynamically during injection (Ex. 1-8). NAKABAYASHI does not appear to expressly disclose a negatively charged polyelectrolyte in the inner fluid (as the MPC co-polymer is zwitteronic and the monomer polymerizes during injection). However, CHU discloses applying an anionic charge modifying agent to a filter membrane (Abstract) where the anionic charge modifying agent is polyelectrolyte, specifically polyacrylic acid (C12/L56-C13/L17, C10/L35).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the teaching of CHU for making the membrane with the teaching of

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Nakabayashi and include the polyelectrolyte of CHU in the “core liquid” of Chu, as in the inner fluid precipitant system of NAKABAYASHI. The suggestion would have been to improve the efficiency of the process by discharging a modifying agent in the inner lumen during the production of the membrane (Pg. 2, Para. 15) thereby reducing the number of steps. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 4, NAKABAYASHI discloses that the dissolved interior filler precipitates in contact with the spinning solution (Ex. 1-8).

As to Claims 5-6, CHU discloses that the proportion by weight of the anionic polymer is at least 0.5% wt and should not exceed 10% wt (C12/L4-17), which overlap the ranges disclosed (0.01 to 10 wt % and 0.05 to 1 wt %).

As to Claims 7-9, NAKABAYASHI discloses polysulfone polymer used as the membrane-forming polymer (Pg. 3, Para. 22) and CHU discloses cellulosic polymer (C7/L22-29) as the membrane-forming polymer.

As to Claim 10, NAKABAYASHI discloses the forming device is a hollow fiber die, which converts the spinning solution into a hollow-fiber with an inner and outer side (Ex. 1-8).

As to Claim 12, CHU discloses a hollow fiber with a supporting and separating layer (C8/L34-38) comprising a polyelectrolyte with a fixed negative charge physically bound on the membrane (C12/L40-48, C10/L35). CHU does not appear to expressly disclose that the supporting layer is free from polyelectrolyte. However, NAKABAYASHI

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discloses interior filler where the outer layer is free from the interior filler (Ex. 1-8) and interior filler is physically bound in the separating layer (Pg. 4, Para. 36-37).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the hollow fiber membrane of CHU to include the supporting layer free from interior filler of NAKABAYASHI. The motivation would have been to have a high performance biocompatible membrane with hydrophobicity maintained on a portion of the membrane by having it free from interior filler (Pg. 2, Para. 10, Pg. 1, Para. 4). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 14, NAKABAYASHI discloses that the separating layer faces the lumen (Claim 9, Pg. 6-7, Para 36-38), where it is implicit that the inner solution coagulates the membrane faster than air resulting in an inner separating layer.

As to Claim 15, CHU discloses that the membrane separates cationic contaminants (C14/L37-53), which implicitly includes proteins, absent evidence to the contrary.

As to Claim 16, NAKAGASHI discloses that the membrane is chemically modified with an agent that reacts with the polyelectrolyte with negative fixed charges (Pg. 4-5, Para. 40-41) and CHU discloses the application of an anionic charged modifying agent (polyelectrolyte) and crosslinking agent to modify the membrane to have negative charges (C13/L32-51, Claim 1).

Response to Arguments

8. Applicant's arguments with respect to claims 1-16 have been considered but are not persuasive in view of the new grounds of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US Patent No. 5,919,370 provides evidence that the precipitant in the inner filling creates the internal separating layer of the hollow fiber.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MC

/Krishnan S Menon/
Primary Examiner, Art Unit 1797